### Remarks

Claims 1-7 and 11-62 are pending and ready for further action on the merits.

Claims 13, 19, and 22 stand rejected under 35 USC § 112, second paragraph, as being indefinite.

Claims 1-7 and 11-61 stand rejected under 35 USC § 103(a) as being unpatentable over US Patent No. 6,613,801 to Mjalli et al. (Mjalli I).

Claims 1-7 and 11-61 stand rejected under 35 USC § 103(a) as being unpatentable over US Patent No. 7,067,554 to Mjalli et al. (Mjalli II).

Claims 1-7 and 11-61 stand rejected on the ground of non-statutory obviousness double patenting as being unpatentable over claims 1-27 of Mjalli I.

Claims 1-7, 11-46, and 61 stand rejected on the ground of non-statutory obviousness double patenting as being unpatentable over claims 1-7 of Mjalli II.

Reconsideration is respectfully requested in light of the above amendments and the following remarks.

# **Amendments**

Various claims have been amended to specifically include pharmaceutically acceptable salts. Support for these amendments can be found in the specification on page page 70, lines 17-19.

Claims 2, 3, 6, 7, 14-17, and 23-40 have been canceled.

Claim 1 has been amended such that  $G_1$  is  $(CH_2)_k$  where k is 1 to 3 instead of k being from 0 to 3. Thus, claim 1 can not read on compounds with an alpha amino acid core structure. Support for this amendment can be found in the specification in Examples 1-3 and 8-12 which are compounds with a beta-amino acid core structure.

Express Mail No. EV 841058421 US Amendments and Response App. Ser. No. 10/091,759 Page 27 of 30

New claims 63-72 have been added. These new claim recite pharmceutical compositions that comprise a compound of Formula (I) or a pharmaceutically acceptable salt thereof. Support for new claims 63-72 can be found in the specification at page 67, line 5, and page 71, lines 11-14.

## Claims 13, 19, and 22 - 35 USC § 112, second paragraph

Claims 13, 19 and 22 are rejected under 35 USC § 112, second paragraph, for allegedly being indefinite.

The Examiner asserts that claim 62 does not exist in the United States Patent and Trademark Office's (USPTO)copy of the claims as filed with the response of April 28, 2005. Applicants respectfully disagree and note that claim 62 appears in the Image File Wrapper of the Patent Application and Image Retrieval (PAIR) System at the USPTO. The Examiner's attention is drawn to the bottom of page 39 of the claims. Claim 62 commences at this page. Claims 13, 19 and 22 depend from claim 62. Accordingly, Applicants believe that none of claims 13, 19 and 22 are indefinite.

Withdrawal of the rejection is warranted and respectfully requested.

### Claims 1-7 and 11-61 - 35 USC § 103(a)

Claims 1-7 and 11-61 stand rejected under 35 USC § 103(a) as being unpatentable over Mjalli I.

Claims 1-7 and 11-61 stand rejected under 35 USC § 103(a) as being unpatentable over Mjalli II.

Applicants traverse.

Claims 2, 3, 6, 7, 14-17, and 23-40 have been canceled rendering the rejection of these claims moot.

Express Mail No. EV 841058421 US Amendments and Response App. Ser. No. 10/091,759 Page 28 of 30

With regard to the remaining claims 1, 4, 5, 11-13, 18-22, and 41-61, Applicants respectfully point out that the subject matter of Mjalli I, Mjalli II, and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Because both of these references would normally be available as prior art under 35 USC § 103(a) through the purview of 35 USC § 102(e), a statement of common ownership at the time of the later invention should be sufficient to remove these references under the provisions of 35 USC § 103(c). In other words, with the above statement of common ownership, these references are not available as prior art.

Withdrawal of the rejection is warranted and respectfully requested.

# Claims 1-7 and 11-61 - Obviousness Type Double Patenting

Claims 1-7 and 11-61 stand rejected under the judicially created ground of non-statutory obviousness type double patenting over claims 1-27 of Mjalli I.

Applicants respectfully traverse.

Claims 2, 3, 6, 7, 14-17, and 23-40 have been canceled rendering the rejection of these claims moot.

With regard to remaining claims 1, 4, 5, 11-13, 18-22, and 41-61, claims 1-27 of Mjalli I do not overlap with the generic formula recited in amended claim 1 of the present application because claims 1-27 of Mjalli I do not read on any compounds within the scope of the genus in amended claim 1. For example, claims 1-27 of Mjalli I do not read on compounds with beta, gamma, or delta amino acid core structures as recited in amended claim 1 of the present application. Further, the specific compounds disclosed in Mjalli I along with the claimed generic formula in Mjalli I do not teach the species recited in claims 11-13 and 18-22 of the present application.

Express Mail No. EV 841058421 US Amendments and Response App. Ser. No. 10/091,759 Page 29 of 30

Thus, withdrawal of the rejection is warranted and respectfully requested.

### Claims 1-7, 11-46, and 61 - Obviousness Type Double Patenting

Claims 1-7 and 11-46, and 61 are rejected under the judicially created ground of non-statutory obviousness type double patenting over claims 1-7 of Mjalli II.

Applicants traverse.

Claims 2, 3, 6, 7, 14-17, and 23-40 have been canceled rendering the rejection of these claims moot.

With regard to remaining claims 1, 4, 5, 11-13, 18-22, 41-46, and 61, claims 1-7 of Mjalli II do not overlap with the generic formula recited in amended claim 1 of the present application because claims 1-7 of Mjalli II do not read on any compounds within the scope of the genus in amended claim 1. For example, claims 1-7 of Mjalli II do not read on compounds with beta, gamma, or delta amino acid core structures as recited in amended claim 1 of the present application. Further, the specific compounds disclosed in Mjalli II along with the claimed generic formula in Mjalli II do not teach the species recited in claims 11-13 and 18-22 of the present application.

Thus, withdrawal of the rejection is warranted and respectfully requested.

#### Fees |

This response is being filed within 6 months of the Office Action mailed July 19, 2006, which set a shortened statutory period of three months for a reply. As a result, a 3-month extension fee is due.

<u>PATENT</u>

Applicants previously paid for 60 claims and for 5 independent claims. Upon entry of these amendments, the total number of claims is 43, and the total number of

independent claims is 1. As a result, no additional claim fee is due.

Should a fee be deemed to be necessary, the Commissioner is hereby

authorized to charge any fees required by this action or any future action to Deposit

Account No. <u>50-4060</u>.

Conclusion

With the above amendments and remarks, Applicants believe that all

objections and/or rejections have been obviated. Thus, each of the claims remaining

in the application is in condition for immediate allowance. A passage of the instant

invention to allowance is solicited.

Should the Examiner have any questions relating to the instant application,

the Examiner is invited to telephone the undersigned at (336) 841-0300 ext. 159 to

discuss any issues.

Respectfully submitted,

Samuel B. Rollins (Reg. No. 52,180)

TransTech Pharma, Inc.

4170 Mendenhall Oaks Pkwy

High Point, NC 27265

Ph: 336-841-0300 ext. 159

Fax: 336-841-0310